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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,595	11/30/2005	John Ong	0501-UTL-0	2750

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Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,595	ONG ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on December 20, 2007 is acknowledged. Under further review, it has come to the Examiner's attention that a preliminary amendment was filed on November 30, 2005 with claims 1-50 filed, not 1-27 as used in the previous restriction requirement. Therefore, the previous restriction requirement is hereby vacated and new restriction requirement follows below.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 9-10 and 27-34, drawn to a pharmaceutical composition comprising exendin or an analog/derivative thereof.

Group 2, claim(s) 11-12, drawn to drawn to a pharmaceutical composition comprising GLP-1 or an analog/derivative thereof.

Group 3, claim(s) 11-12, drawn to drawn to a pharmaceutical composition comprising PYY peptides, agonists or derivative thereof.

Group 4, claim(s) 36, 38, 41 and 43, drawn to a method for transmucosal administration of GLP-1 or an analog/derivative thereof.

Group 5, claim(s) 36-37, 42 and 44, drawn to a method for transmucosal administration of exendin or an analog/derivative thereof.

Group 6, claim(s) 36 and 39-40, drawn to a method for transmucosal administration of PYY peptide or an analog/derivative thereof.

Group 7, claim(s) 45-47 and 50, drawn to a method for increasing the bioavailability of exendin or an analog/derivative thereof following transdermal administration.

Group 8, claim(s) 45-46 and 48, drawn to a method for increasing the bioavailability of GLP-1 or an analog/derivative thereof following transdermal administration.

Group 9, claim(s) 45-46 and 49, drawn to a method for increasing the bioavailability of PYY peptide or an analog/derivative thereof following transdermal administration.

Linking Claims

2. Claims 1-8 and 15-26 link(s) inventions 1 through 3. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-8 and 15-26. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The peptide sequences of exendin, GLP-1 and PYY peptides are patentably independent and distinct due to their amino acid content, leading to different structures. For example, exendin-4 has the sequence HGEGTFTSDLSKQMEEEAVRLFIEWLKNGGPSSGAPPPS and PYY has the sequence YPAKPEAPGEDASPEELSRYYASLRHYLNLVTRQRY (see GenBank Accession No. P68004, titled as PYY.pdf enclosed). The sequences do not share a core sequence, thus each sequence would require an independent search. There is no commonly shared structure. Furthermore, each method Groups are patentably independent and distinct from the other because of the peptide compositions involved in the methods. Again, the sequences do not share a common core sequence or a common structure. Thus, there is lack of unity of invention. Furthermore, the MPEP states the following:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)

(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)

(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

4. In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

5. Additionally, regarding the method claims the MPEP states the following: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent"

claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, a claim to one part referring to another cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim (see MPEP 1850). Therefore, the method claims are in a different category: method of using the products. Therefore, these claims lack unity of invention.

Rejoinder

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Peptide

8. Additionally, Applicant is required to elect a single peptide as the peptide of the compound/composition of the method, as drawn to the elected invention, regardless of which group is elected. [Note: A generic (e.g.-peptide epitope, etc) may NOT be elected as drawn to the elected invention because no meaningful search can be conducted without an undue burden, due to the myriad of potential substitution possible in each formula]. The peptides were not found to share a significant structural core from which a meaningful coextensive search could be conducted, thus a separate and distinct search, as well as examination, of each peptide sequence is required. See also MPEP 803.04 and/or 1850 [Note: All of the alternatives do not have a common property or activity. See references et forth above. Nor is a common structure present]. In order to affect a complete response to this Office Action, Applicant is required to elect a single peptide for examination and identify claims readable upon the elected peptide including any claims subsequently added. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each peptide is**

assumed to be a patentably distinct invention, in the absence of specific, substantial, and credible evidence to the contrary.

9. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

10. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

11. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

12. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

Election of Species

13. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different buffer: acetic acid, ε-aminocaproic acid, or glutamic acid;

Different agents (genera): tonicifying agent, viscosity-increasing agent, a bioadhesive agent, or a preservative agent;

Different cationic polyamino acid: poly-histidine, poly-arginine, or poly-lysine;

Different tonicifying agent: sodium chloride, mannitol, sucrose, or glucose;

Different viscosity-increasing agent: hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, starch or gums;

Different bioadhesive agent: carbomer or polycarophil;

Different preservative: phyenylethyl alcohol, methylparaben, ethylparaben, propylparaben, butylparaben, chlorobutanol, benzoic acid, sorbic acid, phenol, m-cresol, or alcohol;

Different diseases to be treated or ameliorated: food intake, gastric emptying, pancreatic secretion or weight loss.

14. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

15. If Group 1 or 5 or 7 is elected, Applicant is required to elect a single disclosed species of an agent in the composition, cationic polyamino acid. For example, Applicant elects Group 1 and elects glutamic acid buffer, sucrose for tonicifying agent, and methylparaben as preservative. If Group 4 or 5 or 6 is elected, Applicant is further required to elect a single disclosed species of disease or disorder. For example, Applicant elects Group 5 and elects glutamic acid buffer, sucrose for tonicifying agent, and methylparaben as preservative, and further elects pancreatic secretion.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. The claims are deemed to correspond to the species listed above in the following manner:

Claims 4, 7,15-18 and 39.

The following claim(s) are generic: Claims 1, 6, 22-26, 29 and 33.

18. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different buffers are patentably independent and distinct due to their different properties and components. For example, acetate buffer comprises acetic acid, while glutamic acid does not. Further, search for one would not necessarily lead to the other. Different agents (genera) are patentably independent and distinct due to the structure and functions each agent performs. For example, a bioadhesive would act as a "glue" to bind components together while tonicifying agent would not necessarily act to bind

components. Sodium chloride is a salt having a chemical formula NaCl; sucrose is carbohydrate made up of organic composition. Further, search for one would not necessarily lead to the other. Each agent is different in structure and chemical and physical properties, therefore patentably independent and distinct. Further, search for polycarophil (bioadhesive) would not necessarily lead to mannitol. Different cationic polyamino acids are patentably independent and distinct due to their amino acid content, leading to different structures. For example, a search for poly-lysine would not necessarily lead to poly-histidine. Different diseases to be treated or ameliorated (food intake, gastric emptying, pancreatic secretion or weight loss) are patentably independent and distinct due to the organs and cells and mechanisms involved. For example, weight loss would not necessarily involve pancreatic secretion. Further, search for one would not necessarily lead to the other.

19. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

20. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

22. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654